VZCZCXRO5458
RR RUEHDA
DE RUEHAK #0256/01 0480936
ZNR UUUUU ZZH
R 170936Z FEB 10
FM AMEMBASSY ANKARA
TO RUEHC/SECSTATE WASHDC 2141
INFO RUCPDOC/DEPT OF COMMERCE WASHDC
RUEAUSA/DEPT OF HHS WASHDC
RHEHAAA/NSC WASHDC
RUEHIT/AMCONSUL ISTANBUL 6971
RUEHDA/AMCONSUL ADANA 4502

UNCLAS SECTION 01 OF 03 ANKARA 000256

DEPT FOR EUR/SE, EEB/TPP/BTA
DEPT PLEASE PASS USTR FOR MARK MOWREY
COMMERCE FOR ITA/MAC CHERIE RUSNAK AND KRISTIN KNAJDI

SENSITIVE
SIPDIS

E.O. 12958: N/A
TAGS: EINV ECON ETRD EFIN TU
SUBJECT: TURKEY: HEALTH MINISTRY PROPOSES SCENARIOS FOR DRUG APPROVALS

REF: A) ANKARA 143, B) 09 ANKARA 326

This cable is sensitive but unclassified. Please protect accordingly.

¶1. (SBU) Summary. The Ministry of Health (MOH) recognizes that its new rules on Good Manufacturing Practices (GMP) certificates for new drug approvals (described in Ref A) will have some impact on trade in the short term, but is sanguine about the long-term effect. According to Saim Kerman, Director General of Pharmaceuticals and Pharmacies at MOH, the procedural change is aimed at stemming the flow of new generic drugs of questionable quality, for which there are nearly 2000 pending applications, by increasing inspection requirements. He admitted that Turkey does not have the inspection capacity to carry out this new rule, however, and as such may endanger the flow of vital innovative drugs. The GOT has proposed to the pharmaceutical industry five scenarios under which the requirement for an MOH-issued GMP certificate could be waived. Industry analysts tell us the scenarios are problematic, however, and the industry associations are composing a letter to the GOT outlining some of those problems. In addition, recent statements to the press by Kerman's deputy, Halil Akar, suggest a far more protectionist intent to the new rule. He was reported as saying, "Our objective is to encourage local manufacture. We want to make imports of generics more difficult, thereby encouraging the production of original drugs." End summary.

¶2. (SBU) Econ Counselor, Commercial Counselor, and Econoff recently met with Saim Kerman, Director General of Pharmaceuticals and Pharmacies at MOH, to discuss changes to Turkey's rules on accepting GMP certificates issued by other countries that would effectively halt new drug approvals (Ref A).

MOH Looks to Add Flexibility on GMP Acceptance

¶3. (SBU) Kerman acknowledged that Turkey's inspection capacity (currently at around 20 inspectors dedicated to drug facilities, not 11 as previously reported) is insufficient to conduct a GMP inspection of all foreign production plants, and that Turkey is not yet at a stage where it could join a multilateral reciprocal recognition agreements such as the Pharmaceutical Inspection Cooperation Scheme (PIC/S). He noted that the goal of the rule is to stem the flood of applications for generic product imports of questionable quality, many from China and India, the number of which has mushroomed to nearly 2000 over the past year. By increasing the inspection requirements, the GOT hopes to ensure the

safety of products entering its market and also discourage the lowest-quality producers from even applying. He recognized, however, that new drugs would be caught in the same net and so there is a need to introduce some flexibility in the system to allow access for drugs that Turkey needs.

Approval Scenarios

¶4. (SBU) Kerman observed that the GOT had provided to the Association of Research-Based Pharmaceutical Firms (AIFD) a list of scenarios under which the requirement for an MOH-issued GMP certificate could be waived (a GMP certificate issued by another competent authority would still be required). According to Kerman, once AIFD accepts the list it will go to the Undersecretary for approval and then MOH will restart licensing of products that fit the scenarios. The list includes (in order of priority):

-- A pharmaceutical product that is "vitally important";

-- A product that provides a clear medical advantage over existing products, such as increased patient compliance, a more convenient method of administration, a new form of treatment, or a hitherto unmarketed health benefit of a currently marketed product;

-- A product that cannot be manufactured in Turkey, whether for technical reasons (vaccines, blood products, biotechnological products, or a product that requires special manufacturing facilities or packaging) or because the low prescription level of a product or the structure of the

producing company warrants global production;

-- A product that can be manufactured in Turkey where the producer is willing to transfer all or part of the manufacturing process to Turkey (in the case of a product to be manufactured entirely in Turkey, conditional approval can be granted even prior to the submission of relevant test data); or,

-- A product that provides an economic advantage in terms of daily treatment or the cost of treatment, or products that will not apply for reimbursement listing by the Social Security Institute (SSI).

Comment: The list does seem to be geared toward screening out generic products, but the last two categories are illustrative of the GOT's less obvious goal of increasing local production (and thereby adding new jobs) and containing burgeoning health care costs. End comment.

Industry Reaction

¶5. (SBU) Jeffrey Kemprecos, Executive Director of Public Policy and Corporate Responsibility at Merck, described the MOH proposal as problematic at best. He was especially concerned that the list would not be used as a positive tool to exempt needed drugs but rather as a pretext for denying a drug because it is not, for example, sufficiently "innovative" or did not add to "patient convenience." (Note: Merck has previous experience with MOH's use of vague terms like "innovative", as MOH in 2009 violated the data exclusivity of one of Merck's products and then responded to Merck's complaints by arguing that the product in question was insufficiently innovative to merit protection, as described in Ref B. End note.)

¶6. (SBU) Kemprecos noted that the proposals also conflate what should be two separate processes - the decision on whether a drug is safe and effective and the haggling over the specific price. In Turkey, the role of MOH is to determine the former, he argued, with the latter function falling to SSI. He

conceded that MOH's concerns about generics may be valid, but proposed that the way to deal with this is to adopt a risk-based approach to drug approvals rather than a broad change to the rules that seems more focused on cost containment and job creation than on health and safety. He informed us that AIFD had held a meeting in Prague with representatives from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The conclusion of that meeting was that the industry associations would compose a letter offering to support MOH in its goal of improving its inspection capacity and working toward mutual recognition of GMP certificates, but that they would not agree to MOH's offer of exemptions. Comment: It is not clear whether MOH will simply go ahead with the classification system anyway even if AIFD does not agree. End comment.

Blatant Protectionism?

¶7. (SBU) Lending some validity to Kemprecos' fears are recent press statements by Halil Akar, Deputy Director General within Kerman's department. In a statement to the semi-official Anadolu Ajansi, Akar observed "Setting out from the idea that there are very good manufacturing sites in Turkey, we decided to make our country a medicine manufacturing hub of the Middle East and Balkans...Our objective is to encourage local manufacture. We want to make imports of generics more difficult, thereby encouraging the production of original drugs." Akar went on to say that there would be exemptions for some products and that when inspections are necessary priority would be given to essential medicines.

¶8. (SBU) Comment: From discussions with interlocutors at the Foreign Trade Undersecretariat (FTU), it is clear that MOH did not discuss its protectionist ideas with the trade-related agencies (the rule was published in a form that did not require clearance through the Prime Ministry). Kerman acknowledged that the new rule probably violates Turkey's EU Customs Union obligations to allow for the free transit of goods, but waved that problem away with a statement that the

EU ignores its own obligations to Turkey when it is convenient. Should the European Commission decide to insist, this argument is unlikely to pass muster. End comment.

JEFFREY